UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/628,375	07/29/2003	David S. Garvey	102258.158US2	5160

25270 7590 08/10/2006

WILMERHALE/NITROMED
1875 PENNSYLVANIA AVE, NW
WASHINGTON, DC 20006

EXAMINER	
SAEED, KAMAL A	

ART UNIT	PAPER NUMBER
1626	

DATE MAILED: 08/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/628,375	GARVEY ET AL.	
	Examiner	Art Unit	
	Kamal A. Saeed	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 May 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-58* is/are pending in the application.

4a) Of the above claim(s) *3-13,17-27,40-54 and 58* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2, 14-16, 28-39 and 55-57* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-58, are pending in this application. Claims 3-13, 17-27, 40-54 and 58 are withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b), as being drawn to a non-elected invention. The withdrawn subject matter is patentably distinct from the elected subject matter as it differs in structure and element and would require separate search considerations. In addition, a reference, which anticipates one group, would not render obvious the other.

Response to Amendments and Remarks

Applicant's amended claims 1 and 55 to limit the inventions to the elected subject matter. Therefore, the objections of the claims 1,2, 14-16, 28-39 and 55-57 as set forth in the Office Action mailed on 7 February 2006 is hereby with drawn.

During a telephonic conversation with Applicants' representative on July 31, it was agreed on that $-X^2- Y^2-Z^2$ is option (f) i.e $N=CR^4-CR^5$ = and not option (e) as indicated in the amended claim.

Since the product claims have not being found allowable, the restriction between the products and the method of use as set forth in the restriction requirement is maintained.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Applicants preserve their right to file a divisional on the non-elected subject matter.

Double Patenting

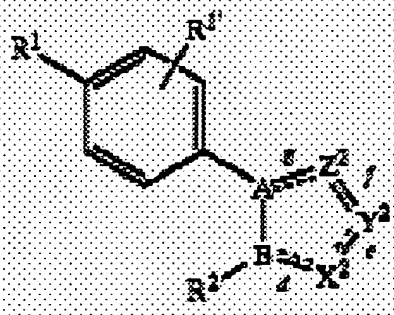
The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1,2, 14-16, 28-39 and 55-57 are rejected under the judicially created doctrine of obviousness-type double patenting, as being unpatentable over claim 1, 2, 14, 15 and 27-37 of U.S. Patent No 6,649,629 B2, since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to the same art recognized subject matter. A reference anticipating one set of claim will render the other obvious. US Patent No. 6,649,629 B2 teach compounds of Formula

II



wherein:

A—B is:

(a) N—C;

(b) C—N; or

(c) N—N;

when sides d and f are double bonds, and sides e and g are single bonds, —X^2—Y^2—Z^2— is:

(a) $=CR^4-CR^{4'}=CR^5-$;

(b) $=N-CR^4=CR^{4'}-$;

(c) $=N-CR^4=N-$;

(d) $=CR^4-N=CR^{4'}-$;

(e) $=CR^4-N=N-$;

(f) $=N-N=CR^4-$;

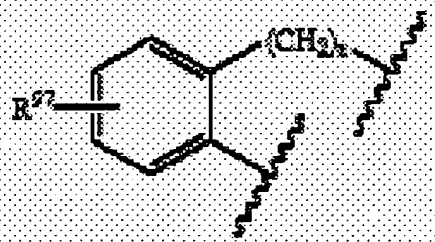
(g) $=N-N=N-$;

(h) $=CR^4-CR^5=N-$; or

(i) $=CR^{2'}-CR^5=N-$;

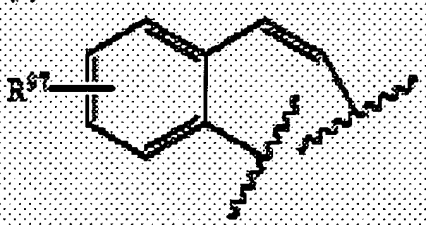
R^2 and $R^{2'}$ taken together are:

(a)



or

(b)



(i) haloalkyl;
(j) hydroxy;
(k) alkoxy;
(l) haloalkoxy;
(m) alkylarylalkylamino;
(n) aminoalkyl;
(o) aminoaryl;
(p) sulfonamido;
(q) alkylsulfonamido;
(r) arylsulfonamido;
(s) heterocyclic ring;
(t) hydroxyalkyl; or
(u) nitro;

a is an integer from 1 to 3;

when sides e and g are double bonds, and sides d and f are single bonds, —X^2—Y^2—Z^2— is:
(a) —CR^4═N—N═;
(b) —N═N—CR^4═;
(c) —CR^4═N—CR^4═;
(d) —N═CR^4—N═;
(e) —CR^4═CR^4—N═;
(f) —N═CR^4—CR^5═;
(g) —CR^4═CR^5—CR^5═; or
(h) —N═N—N═;

when side g is a double bond, and sides d, e and f are single bonds, —X^2—Y^2—Z^2— is:
(a) —C(O)—O—CR^4═;
(b) —C(O)—NR^3—CR^4═;
(c) —C(O)—S—CR^4═; or
(d) —C(H)R^4—C(OH)R^5—N═;

when sides d is a double bond, and sides e, f and g are single bonds, —X^2—Y^2—Z^2— is:
(a) ═CR^4—O—C(O)—;
(b) ═CR^4—NR^3—C(O)—;
(c) ═CR^4—S—C(O)—; or
(d) ═N—C(OH)R^4—C(H)R^5—;

when sides f is a double bond, and sides d, e and g are single bonds, —X^2—Y^2—Z^2— is:
(a) —CH(R^4)—CR^5═N—; or
(b) —C(O)—CR^4—CR^5═;

when sides e is a double bond, and sides d, f and g are single bonds, —X^2—Y^2—Z^2— is:
(a) —N═CR^4—CH(R^5)—; or
(b) —CR^4═CR^5—C(O)—;

when sides d, e, f and g are single bonds, —X^2—Y^2—Z^2— is:
(a) —C(O)—CR^4(R^5)—C(O)—;

R^1 is:
(a) —$S(O)_2$—CH_3;
(b) —$S(O)_2$—$NR^3(D^2)$;
(c) —$S(O)_2$—$N(D^2)$—C(O)—CF_3;
(d) —S(O)—(NH)—$NH(D^2)$;
(e) —S(O)—(NH)—$N(D^2)$—C(O)—CF_3;
(f) —P(O)$(CH_3)NH(D^2)$;
(g) —P(O)$(CH_3)_2$;
(h) —C(S)—$NH(D^2)$;
(i) —S(O)$(NH)CH_3$;
(j) —P(O)$(CH_3)OD^2$; or
(k) —P(O)$(CH_3)NH(D^2)$;

R^2 is:
(a) hydrogen;
(b) halogen;
(c) methyl; or
(d) CH_2OH;

R^2 is:
(a) lower alkyl;
(b) cycloalkyl;

(c) mono-, di- or tri-substituted phenyl or naphthyl, wherein the substituents are each independently:
(1) hydrogen;
(2) halo;
(3) alkoxy;
(4) alkylthio;
(5) CN;
(6) haloalkyl;
(7) lower alkyl;
(8) N_3;
(9) —CO_2D^1;
(10) —CO_2-lower alkyl;
(11) —$(C(R^5)(R^6))_a$—OD^1;
(12) —$(C(R^5)(R^6))_a$—O-lower alkyl;
(13) lower alkyl-CO_2—R^5;
(14) —OD^2;
(15) haloalkoxy;
(16) amino;
(17) nitro;
(18) alkylsulfinyl; or
(19) heteroaryl;
(d) mono-, di- or tri-substituted heteroaryl, wherein the heteroaryl is a monocyclic aromatic ring of 5 atoms, said ring having one heteroatom which is S, O, or N, and, optionally, 1, 2, or 3 additional N atoms; or

the heteroaryl is a monocyclic ring of 6 atoms, said ring having one heteroatom which is N, and, optionally, 1, 2, 3, or 4 additional N atoms;

wherein the substituents are each independently:
(1) hydrogen;
(2) halo;
(3) lower alkyl;
(4) alkoxy;
(5) alkylthio;
(6) CN;
(7) haloalkyl;
(8) N_3;
(9) —$C(R^5)(R^6)$—OD^2;
(10) —$C(R^5)(R^6)$—O-lower alkyl; or
(11) alkylsulfinyl;
(e) benzoheteroaryl which includes the benzo fused analogs of (d);
(f) —$NR^{11}R^{11}$;
(g) —SR^{11};
(h) —OR^{11};
(i) —R^{11};
(j) alkenyl;
(k) alkynyl;
(l) unsubstituted, mono-, di-, tri- or tetra-substituted cycloalkenyl, wherein the substituents are each independently:
(1) halo;
(2) alkoxy;
(3) alkylthio;
(4) CN;
(5) haloalkyl;
(6) lower alkyl;
(7) N_3;
(8) —CO_2D^1;
(9) —CO_2-lower alkyl;
(10) —$C(R^{12})(R^{13})$—OD^2;
(11) —$C(R^{12})(R^{13})$—O-lower alkyl;
(12) lower alkyl-CO_2—R^{12};
(13) benzyloxy;
(14) —O-(lower alkyl)-CO_2R^{12};

(i) haloalkyl;
(j) hydroxy;
(k) alkoxy;
(l) haloalkoxy;
(m) alkylarylalkylamino;
(n) aminoalkyl;
(o) aminoaryl;
(p) sulfonamido;
(q) alkylsulfonamido;
(r) arylsulfonamido;
(s) heterocyclic ring;
(t) hydroxyalkyl; or
(u) nitro;

a is an integer from 1 to 3;

when sides e and g are double bonds, and sides d and f are single bonds, —X^2—Y^2—Z^2— is:
(a) —CR^4═N—N═;
(b) —N═N—CR^4═;
(c) —CR^4═N—CR^4═;
(d) —N═CR^4—N═;
(e) —CR^4═CR^4—N═;
(f) —N═CR^4—CR^5═;
(g) —CR^4═CR^5—CR^5═; or
(h) —N═N—N═;

when side g is a double bond, and sides d, e and f are single bonds, —X^2—Y^2—Z^2— is:
(a) —C(O)—O—CR^4═;
(b) —C(O)—NR^3—CR^4═;
(c) —C(O)—S—CR^4═; or
(d) —C(H)R^4—C(OH)R^5—N═;

when sides d is a double bond, and sides e, f and g are single bonds, —X^2—Y^2—Z^2— is:
(a) ═CR^4—O—C(O)—;
(b) ═CR^4—NR^5—C(O)—;
(c) ═CR^4—S—C(O)—; or
(d) ═N—C(OH)R^4—C(H)R^5—;

when sides f is a double bond, and sides d, e and g are single bonds, —X^2—Y^2—Z^2— is:
(a) —CH(R^4)—CR^5═N—; or
(b) —C(O)—CR^4—CR^5═;

when sides e is a double bond, and sides d, f and g are single bonds, —X^2—Y^2—Z^2— is:
(a) —N═CR^4—CH(R^5)—; or
(b) —CR^4═CR^5—C(O)—;

when sides d, e, f and g are single bonds, —X^2—Y^2—Z^2— is:
(a) —C(O)—CR^4(R^4)—C(O)—;

R^1 is:
(a) —$S(O)_2$—CH_3;
(b) —$S(O)_2$—$NR^5(D^2)$;
(c) —$S(O)_2$—$N(D^2)$—C(O)—CF_3;
(d) —S(O)—(NH)—$NH(D^2)$;
(e) —S(O)—(NH)—$N(D^1)$—C(O)—CF_3;
(f) —P(O)$(CH_3)NH(D^2)$;
(g) —$P(O)(CH_3)_2$;
(h) —C(S)—$NH(D^1)$;
(i) —S(O)(NH)CH_3;
(j) —P(O)$(CH_3)OD^2$; or
(k) —P(O)$(CH_3)NH(D^1)$;

R^2 is:
(a) hydrogen;

(c) mono-, di- or tri-substituted phenyl or naphthyl, wherein the substituents are each independently:
(1) hydrogen;
(2) halo;
(3) alkoxy;
(4) alkylthio;
(5) CN;
(6) haloalkyl;
(7) lower alkyl;
(8) N_3;
(9) —CO_2D^1;
(10) —CO_2-lower alkyl;
(11) —$(C(R^5)(R^5))_2$—OD^1;
(12) —$(C(R^5)(R^5))_2$—O-lower alkyl;
(13) lower alkyl-CO_2—R^5;
(14) —OD^2;
(15) haloalkoxy;
(16) amino;
(17) nitro;
(18) alkylsulfinyl; or
(19) heteroaryl;
(d) mono-, di- or tri-substituted heteroaryl, wherein the heteroaryl is a monocyclic aromatic ring of 5 atoms, said ring having one heteroatom which is S, O, or N, and, optionally, 1, 2, or 3 additional N atoms; or

the heteroaryl is a monocyclic ring of 6 atoms, said ring having one heteroatom which is N, and, optionally, 1, 2, 3, or 4 additional N atoms;

wherein the substituents are each independently:
(1) hydrogen;
(2) halo;
(3) lower alkyl;
(4) alkoxy;
(5) alkylthio;
(6) CN;
(7) haloalkyl;
(8) N_3;
(9) —$C(R^5)(R^5)$—OD^2;
(10) —$C(R^5)(R^5)$—O-lower alkyl; or
(11) alkylsulfinyl;
(e) benzoheteroaryl which includes the benzo fused analogs of (d);
(f) —$NR^{10}R^{11}$;
(g) —SR^{11};
(h) —OR^{11};
(i) —R^{11};
(j) alkenyl;
(k) alkynyl;
(l) unsubstituted, mono-, di-, tri- or tetra-substituted cycloalkenyl, wherein the substituents are each independently:
(1) halo;
(2) alkoxy;
(3) alkylthio;
(4) CN;
(5) haloalkyl;
(6) lower alkyl;
(7) N_3;
(8) —CO_2D^1;

there is a huge overlap in the numerous variables and numerous alternatives of the compounds of Formula II as described in this application and US Patent No. 6,649,629 B2. (See Examples 20d and 20e, col. 89). One of ordinary skill in the art would be motivated to prepare the pyrazole compounds and compositions for pharmaceutical use wherein the compounds could have any of the alternatives of the variables in the Formula described in ` Patent No. `629. The motivation derives from the expectation that structurally similar compounds are generally expected to have similar utilities. In re Gyurik, 596 F. 2d 1012, 201 USPQ 552 (CCPA 1979). Applicants should note that a generic teaching is grounds for obvious type double patenting rejection. In looking at the instantly claimed process as a whole, the claimed process would have been suggested to one skilled in the art unless unobvious or unexpected results can be shown.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kamal A Saeed, Ph.D. whose telephone number is (571) 272-0705. The examiner can normally be reached on M-T 7:00 AM- 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Joseph K. McKane, can be reached at (571) 272-0699.

Communication via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signiture, may be used by applicant and should be addressed to [joseph.mckane@uspto.gov]. All Internet e-mail communications will be made of record in the application file. PTO employees will not communicate with applicant via Internet e-mail where sensitive data will be exchanged or where there exists a possibility that sensitive data could be identified unless there is of record an express waiver of the confidentiality

requirements under 35 U.S.C. 122 by the applicant. See the Interim Internet Usage Policy published by the Patent and Trademark Office Official Gazette on February 25, 1997 at 1195 OG 89.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or public PAIR only. For more information about the pair system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197.

KAMAL A. SAEED, PH.D
PRIMARY EXAMINER